UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,306	04/17/2001	Robert C. Ladner	DYAX/002	9730

7590 07/11/2003

James F. Haley, Jr., Esq.
FISH & NEAVE
1251 Avenue of the Americas
New York, NY 10020-1104

EXAMINER	
EPPERSON, JON D	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 07/11/2003 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,306	LADNER ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-2, 10-36 (in part) drawn to a method for "cleaving single-stranded nucleic acid sequences at a desired location", classified variously in class 435, subclass 91.1.

   II. Claims 3-6, 10-36 (in part) drawn to a method for "displaying a member of a diverse family of peptides ... on the surface of a genetic package", classified variously in class 435, subclass 91.2+; class 435, DIG 3.

   III. Claims 7-9, drawn to a product described as a library, classified variously in class 435, subclass 6, subclass 478; class 435, DIG 23; class 435, subclass 320.1.

   IV. Claims 37-41 drawn to a method for "preparing single-stranded nucleic acids for cloning into a vector", classified variously in class 435, subclass 91.4+.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I-IV represent separate and patentably distinct inventions. Groups I-II and IV are drawn to different methods and Groups III is drawn to a different product (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for

the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents.

4. Groups I, II and IV represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. . In the instant case, Group II requires "a genetic package" (e.g., phage), which is not required by Groups I and IV. Likewise Group IV requires method steps for the preparation of a "vector", which is not required by the method of Group I. Therefore, Groups I, II and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

5. Groups I-IV represent patentably distinct methods and products. However, if applicant were to argue that any of Groups I, II and IV are somehow related to Group III as process of making and product made, the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different

process (MPEP § 806.05(f)). In the instant case, (2) the product as claimed can be made by another materially different process e.g., the oligonucleotide synthesis without restriction enzymes.

6. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

7. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

8. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of nucleic acid (see claim 1)

A. Single Stranded
B. Partially double stranded

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid from the list above i.e., A or B.

Subgroup 2: Species of what nucleic acid encodes (see claims 11-19)

Applicant must elect, for the purposes of search, a ***single species*** of what the nucleic acid encodes e.g., human FR1. Please do not elect a broad category of molecules like immunoglobulin as more than one species would be erroneously elected. Please also

indicate the nucleic acid source (i.e., human) and indicate whether it is a heavy or light chain.

Subgroup 3: Species of autoimmune disease (see claim 18)

Applicant must elect, for the purposes of search, a ***single species*** of autoimmune disease e.g., lupus, erythematosus.

Subgroup 4: Species of isolated cells (see claim 20)

Applicant must elect, for the purposes of search, a ***single species*** of isolated cells e.g., blood cells, bone marrow cells.

Subgroup 5: Species of amplification (see claims 21-22)

Applicant must elect, for the purposes of search, a ***single species*** of amplification e.g., no amplification, amplification with geneRACE.

Subgroup 6: Species of temperature (see claims 23-25)

Applicant must elect, for the purposes of search, a ***single species*** of temperature e.g., 55°C.

Subgroup 7: Species of single-stranded oligonucleotide length (see claims 26-27)

Applicant must elect, for the purposes of search, a ***single species*** of oligonucleotide length e.g., 20 bases.

Subgroup 8: Species of temperature (see claims 23-25)

Applicant must elect, for the purposes of search, a ***single species*** of temperature e.g., 55°C.

Subgroup 9: Species of restriction endonuclease (see claims 28-29)

Applicant must elect, for the purposes of search, a ***single species*** of restriction endonuclease e.g., MaeIII, Tsp45I.

Subgroup 10: Species of length of single-stranded region of double stranded oligonucleotide (see claims 31-32)

Applicant must elect, for the purposes of search, a ***single species*** of length e.g., 6 bases.

9. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 3 is generic.

Subgroup 1: Species of nucleic acid (see claim 3)

A. Single Stranded
B. Partially double stranded

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid from the list above i.e., A or B.

Subgroup 2: Species of what nucleic acid encodes (see claims 11-19)

Applicant must elect, for the purposes of search, a ***single species*** of what the nucleic acid encodes e.g., human FR1. Please do not elect a broad category of molecules like immunoglobulin as more than one species would be erroneously elected. Please also indicate the nucleic acid source (i.e., human) and indicate whether it is a heavy or light chain.

Subgroup 3: Species of autoimmune disease (see claim 18)

Applicant must elect, for the purposes of search, a ***single species*** of autoimmune disease e.g., lupus, erythematosus.

Subgroup 4: Species of isolated cells (see claim 20)

Applicant must elect, for the purposes of search, a ***single species*** of isolated cells e.g., blood cells, bone marrow cells.

Subgroup 5: Species of amplification (see claims 21-22)

Applicant must elect, for the purposes of search, a ***single species*** of amplification e.g., no amplification, amplification with geneRACE.

Subgroup 6: Species of temperature (see claims 23-25)

Applicant must elect, for the purposes of search, a ***single species*** of temperature e.g., 55°C.

Subgroup 7: Species of single-stranded oligonucleotide length (see claims 26-27)

Applicant must elect, for the purposes of search, a ***single species*** of oligonucleotide length e.g., 20 bases.

Subgroup 8: Species of temperature (see claims 23-25)

Applicant must elect, for the purposes of search, a ***single species*** of temperature e.g., 55°C.

Subgroup 9: Species of restriction endonuclease (see claims 28-29)

Applicant must elect, for the purposes of search, a ***single species*** of restriction endonuclease e.g., MaeIII, Tsp45I.

Subgroup 10: Species of length of single-stranded region of double stranded oligonucleotide (see claims 31-32)

Applicant must elect, for the purposes of search, a ***single species*** of length e.g., 6 bases.

Subgroup 11: Species of genetic package (see claims 3-6)

Applicant must elect, for the purposes of search, a ***single species*** of genetic package e.g., phage.

10. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 7 is generic.

Subgroup 1: Species of nucleic acid (see claims 7-9)

A. Single Stranded
B. Partially double stranded

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid from the list above i.e., A or B.

Subgroup 2: Species of what nucleic acid encodes (see claims 11-19)

Applicant must elect, for the purposes of search, a ***single species*** of what the nucleic acid encodes e.g., human FR1. Please do not elect a broad category of molecules like immunoglobulin as more than one species would be erroneously elected. Please also indicate the nucleic acid source (i.e., human) and indicate whether it is a heavy or light chain.

Subgroup 3: Species of autoimmune disease (see claim 18)

Applicant must elect, for the purposes of search, a ***single species*** of autoimmune disease e.g., lupus, erythematosus.

Subgroup 4: Species of isolated cells (see claim 20)

Applicant must elect, for the purposes of search, a ***single species*** of isolated cells e.g., blood cells, bone marrow cells.

Subgroup 5: Species of amplification (see claims 21-22)

Applicant must elect, for the purposes of search, a ***single species*** of amplification e.g., no amplification, amplification with geneRACE.

Subgroup 6: Species of temperature (see claims 23-25)

Applicant must elect, for the purposes of search, a ***single species*** of temperature e.g., 55°C.

Subgroup 7: Species of single-stranded oligonucleotide length (see claims 26-27)

Applicant must elect, for the purposes of search, a ***single species*** of oligonucleotide length e.g., 20 bases.

Subgroup 8: Species of temperature (see claims 23-25)

Applicant must elect, for the purposes of search, a ***single species*** of temperature e.g., 55°C.

Subgroup 9: Species of restriction endonuclease (see claims 28-29)

Applicant must elect, for the purposes of search, a ***single species*** of restriction endonuclease e.g., MaeIII, Tsp45I.

Subgroup 10: Species of length of single-stranded region of double stranded oligonucleotide (see claims 31-32)

Applicant must elect, for the purposes of search, a ***single species*** of length e.g., 6 bases.

Subgroup 11: Species of genetic package (see claims 3-6)

Applicant must elect, for the purposes of search, a ***single species*** of genetic package e.g., phage.

11. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 15 and 16 below).

12. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

15. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement***, ***and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

16. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

18. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

19. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
June 30, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER